

STATE OF MICHIGAN  
DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES  
Before the Director of Insurance and Financial Services

In the matter of:

██████████

Petitioner,

v

File No. 145687-001

Blue Cross Blue Shield of Michigan,  
Respondent.

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Issued and entered  
this 5<sup>th</sup> day of February 2015  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

On January 7, 2015, ██████████ (Petitioner) filed a request with the Director of Insurance and Financial Services for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* After a preliminary review of the material submitted, the Director accepted the request on January 14, 2015.

The Petitioner receives prescription drug benefits through a group plan underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The Director notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. BCBSM provided its response on January 26, 2015.

To address the medical issues in the case, the Director assigned it to an independent medical review organization which provided its analysis and recommendation on January 28, 2015.

**II. FACTUAL BACKGROUND**

The Petitioner's prescription drug benefits are defined in BCBSM's *Preferred RX Program Certificate SG<sup>1</sup>* (the certificate).

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<sup>1</sup> BCBSM form no. 910F, federal approval 09/13, state approval 03/14.

The Petitioner has a history of chronic pain and lumbago for which she has tried and failed several prescription pain relievers. Because she still has breakthrough pain, her physician requested prior authorization for the prescription drug Subsys. BCBSM denied the request.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process BCBSM affirmed its denial in a final adverse determination dated December 11, 2014. The Petitioner now seeks a review of that adverse determination from the Director.

### III. ISSUE

Did BCBSM correctly deny preauthorization and coverage for the prescription drug Subsys?

### IV. ANALYSIS

#### Petitioner's Argument

The Petitioner stated in her request for an external review:

I was previously taking Oxycontin for pain then that was not covered, so [my doctor] wanted to try Subsys and now that has been denied. This has been helping with no side effects so I would like to keep [it].

In an appeal letter to BCBSM dated November 24, 2014, the Petitioner's pain specialist explained the reasons for requesting coverage of Subsys:

[The Petitioner] is a 42 year-old female with chronic pain syndrome, and Lumbago. The patient is in almost constant severe pain on a daily basis. The pain gives the patient a significantly limited quality of life. [She] is unable to sit, stand, walk or reach - which includes participating in family life and riding in automobiles for more than 2 to 3 hours per day.

In an effort to control her pain and improve her quality of life, she has tried and failed the medications listed: Norox, Oxy Contin, MSIR, Ms Contin, Fentanyl Patch, and Kadian.

A combination of the medicines for pain, at the highest dose available, tends to abate her pain however, frequent episodes of severe breakthrough pain are not being controlled adequately. It is clearly evident that severe breakthrough pain continues to be a problem with a frequency that is debilitating to this patient. Injectable pain relievers are not an option for this patient.

Due to the severity of [the Petitioner's] illness and pain, and due to the limited number of medications available to her, I write this letter recommending that coverage be approved for Subsys Spray 200 mcg to control her breakthrough pain as a medical necessity for offering this patient as much quality of life as possible.

### BCBSM's Argument

In its final adverse determination, BCBSM explained to the Petitioner its reasons for denying preauthorization for Subsys:

You are covered under the *Preferred RX Program Certificate SG*. As indicated on Page 2.6 of the *Certificate*, for some drugs certain clinical criteria must be met before coverage is provided. In the case of drugs requiring step therapy, for example, previous treatment with one or more preferred drugs may be required.

\* \* \*

A Clinical Pharmacist reviewed the records submitted with your appeal and determined:

The requested medication is excluded from coverage under your Custom Select drug plan. Covered alternatives include: generic Dilaudid, generic OxyIR. Please refer to your Custom Select drug list for a complete list of covered alternatives. Please note: Subsys is only indicated for the management of breakthrough pain in adult cancer patients. Per FDA labeling, "SUBSYS is intended to be used only in the care of cancer patients."

### Director's Review

The certificate (p. 2.6) says, "For some drugs certain clinical criteria must be met before coverage is provided." According to BCBSM's coverage criteria, Subsys will not be approved unless the patient has a diagnosis of breakthrough cancer pain - which the Petitioner does not have. Therefore, BCBSM declined to cover the drug Subsys ruling the Petitioner did not meet its criteria for use of this drug.

The question of whether BCBSM's denial of coverage of Subsys was medically appropriate given the Petitioner's condition was presented to an independent review organization (IRO) as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The IRO physician reviewer is board certified in anesthesiology and pain management and has been in practice for more than ten years. The IRO reviewer's report included the following analysis and recommendation:

The MAXIMUS physician consultant indicated that a review of the information provided for review suggests that the member has pain that is poorly responsive to opiates. The physician consultant also indicated that putting the member on higher doses will not effectively treat her pain if the underlying pain is not opiate responsive. There was no documentation submitted in the case file to show that anti-convulsants such as gabapentin and pregabalin have been tried in this member's case. There was also no evidence provided for review to show that the member has tried non-steroidal anti-inflammatory medications, muscle relaxants or tricyclic anti-depressants. There were also no urine toxicology screens provided for review and no documentation of an opiate maintenance agreement.

The physician consultant explained that furthermore, the choice of Subsys is not appropriate for this member. (Physicians Desk Reference 2014, Package Insert for Subsys.) The consultant also explained that the use of a transmucosal immediate-release fentanyl (TIRF) medication for treatment of low back pain is not supported by any large scale clinical trial. The Transmucosal Immediate Release Fentanyl Products Risk Evaluation and Mitigation Strategy (TRIF REMS) Access Program, which includes Subsys states that "TIRF medicines are indicated only for the management of breakthrough pain in adult patients with cancer 18 years and older who are already receiving and who are tolerant to regular opioid therapy for underlying persistent cancer pain. . . . The consultant noted that there is not an exception process or compassionate use clause in this program.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that Subsys is not medically necessary for treatment of the member's condition.

The Director is not required to accept the IRO's recommendation. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). However, the IRO's recommendation is afforded deference by the Director. In a decision to uphold or reverse an adverse determination the Director must cite "the principal reason or reasons why the [Director] did not follow the assigned independent review organization's recommendation." MCL 550.1911(16)(b). The IRO's analysis is based on extensive experience, expertise, and professional judgment. In addition, the IRO recommendation is not contrary to any provision of the Petitioner's certificate of coverage. MCL 550.1911(15).

The Director, discerning no reason why the IRO's recommendation should be rejected, finds that Subsys is not medically necessary to treat the Petitioner's condition.

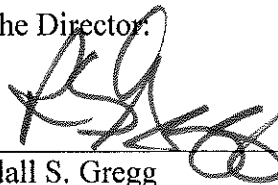
**V. ORDER**

The Director upholds BCBSM's final adverse determination of December 11, 2014.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this order may seek judicial review no later than 60 days from the date of this order in the circuit court for the Michigan county where the covered person resides or in the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Department of Insurance and Financial Services, Office of General Counsel, Post Office Box 30220, Lansing, MI 48909-7720.

Annette E. Flood  
Director

For the Director:

A handwritten signature in dark ink, appearing to read 'R. S. Gregg', is written over a horizontal line.

Randall S. Gregg  
Special Deputy Director